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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/598,597	10/11/2007	John E. Davies	058376-0003	7537
46127 7590 01/19/2012 HEENAN BLAIKIE LLP BAY ADELAIDE CENTRE 333 BAY STREET, SUITE 2900, P.O. BOX 2900 TORONTO, ON M5H 2T4 CANADA				
EXAMINER				
EPPS -SMITH, JANET L				
ART UNIT		PAPER NUMBER		
1633				
NOTIFICATION DATE		DELIVERY MODE		
01/19/2012		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/598,597

Applicant(s)

DAVIES ET AL.

Examiner

Janet Epps-Smith

Art Unit

1633

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 November 2011.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 4-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 4-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Transposition's Patent Drawing Review (PTO-848)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. Claims 1-2, and 4-16 are pending for examination.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

3. The rejection of claims 13 and 16 under 35 U.S.C. 112, 5th paragraph, as being in improper multiple dependent form is withdrawn in response to Applicant's amendment.
4. The rejection of claims 2-8 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, is withdrawn in response to Applicant's amendment.
5. Claims 1-2, 4-8, and 13-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
6. Claim 1 has been amended to recite the following;
 1. (Currently Amended) A process for expanding a stem and/or progenitor cell population, comprising the step of culturing an input population of mesenchymal progenitor cells by non-static non-adherent suspension in serum-deprived nutrient medium.
7. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent

protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 1 recites the broad recitation "a stem and/or progenitor cell population," and the claim also recites "mesenchymal progenitor cells," which is the narrower statement of the range/limitation.

Claim Rejections - 35 USC § 102

8. The rejection of claims 1-3, and 8, and 13-16 under 35 U.S.C. 102(b) as being anticipated by Baksh et al. (WO02/086104A1; ¶ numbers cited below are taken from the US patent application 20040137612), is withdrawn in response to Applicant's amendment and arguments.
9. Claims 9-12 remain rejected under 35 U.S.C. 102(b) as being anticipated by Baksh et al. (WO02/086104A1; ¶ numbers cited below are taken from the US patent application 20040137612), for the reasons of record.
10. Applicant's arguments filed 11-16-2011 were fully considered, however they did not specifically address the rejection of claims 9-12.

11. Regarding the population of cells recited in claims 9-12, specifically the CD45-/CD123 (IL3+) cells, see Figure 7, and paragraph [0059] of this reference. Figure 7 clearly shows the expansion of CD45- progenitor cells in the presence of CD123 (IL3). Thus, the population represented by Figure 7 reads on the instant claims.

Claim Rejections - 35 USC § 102

12. The rejection of claims 1-2, 7-8, 11, and 13-15 under 35 U.S.C. 102(a) as being anticipated by Kallos et al. (2003), is withdrawn in response to Applicant's amendment to claim 1.

Claim Rejections - 35 USC § 103

13. Claims 1-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baksh et al. WO 2002/086104 and in view of Cancedda et al. (US 6617159).

14. Applicants traversed the instant rejection on the grounds that the culturing conditions of Cancedda et al. included the use of anchorage dependent methods. Moreover, Applicants argued that the person of ordinary skill in the art would have expected that growing mesenchymal cells in anchorage independent conditions in serum-free medium would actually induce differentiation. Contrary to Applicant's assertions, Applicants have not provided any evidence that the medium for expanding mesenchymal cells, as disclosed by this reference would result in differentiation of mesenchymal progenitor cells. Applicant's arguments do not take the place of evidence of non-obviousness.

15. The methods of Baksh et al. clearly encompass a method for expanding mesenchymal progenitor cells. See the following at page 50:

A method for expanding human non-hematopoietic progenitor cells, the method comprising the step of subjecting a progenitor cell population comprising non-hematopoietic progenitor cells to non-static suspension culturing in a suitable medium for a period of time effective to expand said progenitor cells.

The method according to claim 5 wherein said progenitor cell population comprises human mesenchymal progenitor cells.

The method according to claim 5, wherein said progenitor cell population is an enriched progenitor cell population according to any one of claims 1-4.

The method according to any one of claims 5-7, wherein said growth medium includes growth factors for human mesenchymal progenitor cells.

The method according to any one of claims 5-7, wherein the growth medium excludes at least one factor specific for the growth of hematopoietic progenitor cells.

The method according to claim 8 or claim 9 wherein said growth factors are cytokines.

The method according to claim 10 wherein said cytokines are a mixture of stem cell factor and interleukin-3.

The method according to any one of claims 5-10, wherein said suspension is stirred during said effective period of time.

16. The method of Baksh et al. includes guidance for designing a growth medium for the population of cells expanded in this method. Specifically, the medium includes at least one growth factor for the growth of hematopoietic progenitor cells, wherein said factors are cytokines.

17. One of ordinary skill in the art at the time of the instant invention, following the teachings of Baksh et al. would have been motivated to use a medium comprising cytokines in the method for expanding mesenchymal progenitor cells.

18. Cancedda et al. "[A]lso provided for mesenchymal stem cell growth, is a serum free medium which includes a composition comprising FGF-2, LIF, SCF, pantotenate, biotin and selenium and method, therefore." There are no limitations set forth in the issued claims which would limit the issued method to only anchorage dependent culturing conditions. Furthermore, the product claims drawn to a serum free culture medium, do not appear to be limited to only anchorage dependent methods.

Conclusion

19. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

1. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet Epps-Smith whose telephone number is (571)272-0757. The examiner can normally be reached on M-F, 10AM-6:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on (571)-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Janet L. Epps-Smith/
Primary Examiner, Art Unit 1633